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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/973,265   | 10/09/2001  | Ashok Rampal         | RLL-124CIPUS        | 8161             |
| 26815  | 7590        | 07/15/2005           | EXAMINER            |                  |
| RANBAXY INC.<br>600 COLLEGE ROAD EAST<br>SUITE 2100<br>PRINCETON, NJ 08540 |             |                      | LUKTON, DAVID       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1654                |                  |

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |               |
|------------------------------|-----------------|---------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |
|                              | 09/973,265      | RAMPAL ET AL. |
|                              | Examiner        | Art Unit      |
|                              | David Lukton    | 1654          |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 March 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5-16,20-27 and 29-47 is/are pending in the application.
- 4a) Of the above claim(s) 8,15,16,20 and 30-47 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,6,7,14,21-23 and 27 is/are rejected.
- 7) Claim(s) 5,9-13,24-26 and 29 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

Pursuant to the directives of the response filed 3/22/05, claims 4, 17-19, 28 have been cancelled, and the following claims amended: 1-3, 5-16, 21-23, 27, 29. Claims 1-3, 5-16, 20-27, 29-47 are now pending.

Applicants' arguments filed 3/22/05 have been considered and found persuasive in part. Claims 8, 15, 16, 20, 30-47 remain withdrawn from consideration. Claims 1-3, 5-7, 9-14, 21-27, 29 are examined in this Office action.

\*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 7, 14, 21-23, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Lee (USP 6,228,400).

As indicated previously, Lee discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer.

In response, applicants have (a) required that the composition of claim 1 contain a water-soluble polymer, and (b) introduced the term "pellet" into claim 27.

Applicants have argued that Lee does not disclose water-soluble polymers. However, Lee does disclose these, such as cellulose, cellulose derivatives, and polyethylene glycol. Applicants have also argued that Lee does not suggest a formulation which contains pellets or beads. However, much depends on the exact definition of the terms at issue, and in particular the size limitations. Lee discloses (col 6, line 49) "drug-coated spherical particles". These particles are large enough to qualify as "beads", in the absence of any size limitation on the latter.

The rejection is maintained.

\*

Claims 1, 6, 7, 14, 21-23, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Bergstrand (WO 96/01623).

Bergstrand discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer. Core materials are discussed at page 7, line 21+.

In response, applicants have (a) required that the composition of claim 1 contain a water-soluble polymer, and (b) introduced the term "pellet" into claim 27.

Applicants have argued that Lee does not disclose water-soluble polymers. However, Bergstrand does disclose these, such as cellulose, and cellulose derivatives.

Applicants have also argued that Bergstrand does not suggest a formulation which contains pellets or beads. However, the term "pellet" is referred to no fewer than 137 times in the document.

The rejection is maintained.

◆

Claims 1-3 are rejected under 35 U.S.C. §102(b) as being anticipated by Lovgren (USP 4,786,505).

As indicated previously, Lovgren discloses a composition comprising omeprazole and PVP.

In response, applicants have required that the composition of claim 1 contain a water-soluble polymer, and have argued that Lovgren does not disclose this. However, there are numerous references to water-soluble polymers such as cellulose and PEG.

The rejection is maintained.

◆

Claims 1, 6, 7, 14, 21-23, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Henriksen (USP 6,391,342).

As indicated previously, Henriksen discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer which can be cross-linked PVP.

In response, applicants have (a) required that the composition of claim 1 contain a water-soluble polymer, and (b) introduced the term "pellet" into claim 27.

Applicants have argued that Henriksen does not disclose water-soluble polymers. However, Henriksen does disclose these, such as cellulose, cellulose derivatives, and polyethylene glycol. Applicants have also argued that the term "pellet" is not used in Henriksen. However, the term "pellet" occurs at least 18 times in the patent.

The rejection is maintained.

\*

Claim 27 is rejected under 35 U.S.C. §102(e) as being anticipated by Ballester Rodes (USP 5626875).

Ballester Rodes discloses (e.g., col 2, line 13+) a composition comprising a neutral core to which is applied a mixture comprising omeprazole, followed by an intermediate layer, and a third layer.

Thus, the claim is anticipated.

\*

The following is a quotation of 35 U.S.C. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 6, 7, 14, 21-23, 27 are rejected under 35 U.S.C. §103 as being unpatentable over Chen (USP 6,096,340).

Chen discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-soluble polymer. Chen does not disclose using cross-linked PVP. However, the use of cross-linked PVP is well known to drug formulation specialists who formulate omeprazole-containing compositions. The degree of cross linking affects the rate of dissolution. The drug formulation specialist of ordinary skill would have been motivated to use cross linked PVP to reduce the rate of dissolution.

In response, applicants have (a) required that the composition of claim 1 contain a water-soluble polymer, and (b) introduced the term "pellet" into claim 27.

Applicants have argued that Henriksen does not disclose water-soluble polymers. However, Henriksen does disclose these, such as cellulose, and cellulose derivatives. Applicants have also argued that the term "pellet" is not used in Chen. However, this term is used, e.g., in col 3, line 58.

The rejection is maintained.

♦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

  
DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800